EXHIBIT D

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Donna Plahmer, et al. v. Ethicon, Inc.., et al No. 2:12-cv-00878	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Marc J. Bern and Partners Law Firm to give medical opinions related to Donna Plahmer. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based

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slings, and periurethral bulking procedures. I have attended training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records pertaining to Donna Plahmer:

- Saint Michael's Hospital;
- Ministry Medical Group;
- Alfred L. Neuhoff, Jr., MD;
- Ministry Saint Michael's Hospital-Radiology and Medical Records Departments;
- Aspirus Stevens Point Clinic

In addition, I have reviewed the following medical literature, relevant depositions and other TVM-related documents (provided separately as my reliance list) in assisting in the formulation of my opinions.

Clinical History

- On April 23rd, 2003, Mrs. Donna Plahmer was seen by Dr. Hien Vo-Hill, presenting as a 49 year-old female G3P2 with urinary

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incontinence and menometrorrhagia. Her urinary urgency incontinence was effectively treated with Detrol LA at that time. She was noted to have nocturia x3. There was no history or complaints of dyspareunia or increased frequency at that time. Her past medical history was in part remarkable for hypertension, irritable bowel syndrome, restless leg syndrome, and [redacted] Physical exam revealed no vaginal atrophy, a grade 2 rectocele, and urethral hyper mobility.

- On August 5th, 2003, Dr. Vo-Hill performed a laparoscopic assisted vaginal hysterectomy and bilateral salpingooophorectomy, posterior colporrhaphy, and placement of tension free transvaginal tape. She had been previously diagnosed with menometrorrhagia, mixed urinary incontinence (MUI) with component of urethral hypermobility and mild uterovaginal prolapse, and a second degree rectocele. She was discharged home on post-operative day 3 having had an uneventful post-operative recovery.

- On September 2nd, 2003, Dr. Vo-Hill saw Mrs. Plahmer in follow-up having recently reapproximated her posterior vaginal mucosal sutures secondary to partial breakdown. She suture-revised two areas in the vagina (one near the hymenal ring and the other along the posterior vaginal wall) and prescribed Silvadene for subsequent wound care.

- On October 2nd, 2003, Dr. Vo-Hill saw Mrs. Plahmer in follow-up. She had recovered well from surgery, denying excessive pain or incontinence. She was prescribed Detrol LA and Premarin cream.

- Between 2003 and 2007, multiple medical records indicate that Mrs. Plahmer was on several different anticholinergic medications used to treat overactive bladder (OAB) and urgency urinary incontinence (UUI).

- On May 8th, 2007, Mrs. Plahmer was treated for a UTI.

- On May 29th, 2007 she presented to St. Michael's emergency room with dysuria

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- On October 4th, 2013, Mrs. Plahmer underwent a CT scan of the Abdomen and Pelvis which demonstrated a distended bladder and prominent bilateral renal pelves.

- On October 30th, 2015, she presented to Aspirus Wausau Hospital with dysuria and low back pain She was taking Vesicare 10 mg daily

- On November 25th, 2015 she was empirically treated for a UTI after presenting with worsening urinary incontinence. She continued to be on Vesicare 10 mg daily.

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2003 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

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ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

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General Opinion No. 2

Safer alternatives designs and procedures existed in 2010 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2003, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Plahmer was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Vo-Hill was unable to warn Mrs. Plahmer of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Plahmer suffered vaginal sling contraction, as a result of the physical properties of the TVT device. These conditions are documented in the medical records and are evidenced by the development of vaginal stenosis as well as worsening urgency urinary incontinence symptoms. Additionally, Mrs. Plahmer's medical records suggest that she had issues emptying her bladder, as evidenced by a CT scan in 2013 showing a distended bladder and dilated upper urinary tracts.

A. Contraction/Shrinkage

Mrs. Plahmer's TVT contracted post implantation. Despite being initially placed in a tension free fashion consistent with the IFU, the TVT contracted. In the setting of mesh contraction, patients typically develop worsening urinary incontinence because of extensive fibrosis around the urethra. This diminishes the compliance of the urethral tissues making it difficult to control urinary flow. Paradoxically, patients typically develop worsening urgency and urgency urinary incontinence in the setting of incomplete bladder emptying.

I have observed patients in my clinical practice who develop worsening voiding dysfunction that is the result of post-implantation contraction or shrinkage of the mesh.

Case Specific Opinion No. 2

Ms. Plahmer's vaginal pain and dyspareunia was caused in part by excessive scarring and resultant contraction of the TVT device. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5)

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infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; and (8) pelvic floor dysfunction. [1]

I am able to rule in contraction and scarring as potential causes of Mrs. Plahmer's vaginal pain and dyspareunia. These conditions are documented in her deposition. Of note, her dyspareunia started soon after her TVT surgery (in 2004). It is also possible that her other procedures may have contributed to her dyspareunia as well. The development of significantly worsening voiding dysfunction following this surgery, however, more directly links the TVT as a predominate causative factor in Mrs. Plahmer's development of pelvic pain and dyspareunia as the scarring and contraction related to her mesh has contributed both to her voiding dysfunction and dyspareunia.

Neuromuscular injury is excludable as the cause of Mrs. Plahmer's dyspareunia. Although she did suffer with lower back and sacroiliac pain, this was never associated directly with her dyspareunia.

Vaginal tissue atrophy is a plausible contributing factor as a cause of Mrs. Plahmer's dyspareunia. However, her dyspareunia started soon after her TVT surgery and the development of estrogen-related atrophy occurred sometime after this. The chronology regarding the development of her dyspareunia makes this a less significant causative factor.

I am able to exclude pelvic floor dysfunction, paraurethral banding, and lichen sclerosis as causes of Mrs. Plahmer's dyspareunia as she has never been diagnosed with these conditions.

Case Specific Opinion No. 3

Mrs. Plahmer's future prognosis as it relates to her pelvic pain, dyspareunia, and voiding dysfunction is guarded. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. Moreover, the surgery she has already had performed by Dr. Vo-Hill has resulted in residual fibrosis and scarring in the area of her sling and also (likely to a lesser degree) where her posterior colporraphy was performed. I anticipate that if further surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure. Additionally, she has suffered the complication of

[1] (Ashok, 2012)

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vaginal stenosis in the area of her sling that has rendered her with such a narrowed vaginal canal that intercourse is both near impossible if not very painful

In as much as physical therapy might be somewhat helpful at improving her pelvic pain and dyspareunia, they most certainly will not resolve the symptoms she currently suffers from. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, pelvic pain, and dyspareunia will be a lifelong condition for this patient. Moreover, alternative successful and safer sling procedures were available at the time of her original synthetic mesh sling implantation, including the use of a biologic graft or an autologous fascial sling with suture. These safer alternative sling procedures would not have resulted in the same symptoms and injuries that Mrs. Plahmer now suffers.

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.

Sincerely,

Konstantin Walmsley, M.D.

4/17/17